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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RANDAL K. BUDDINGTON, JAN VAN LOO, and
ANNE FRIPPIAT

Appeal 2007-3269
Application 09/671,106
Technology Center 1600

Decided: January 15, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and FRANCISCO C.
PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a treating infections. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

THE INVENTION

“The present invention . . . relates to a method for inhibiting the systemic growth of pathogenic bacteria in humans and vertebrates by administration of a composition containing a dietary fiber, particularly a

fructan” (Spec. 1). Fructans useful in the disclosed treatment methods include “inulin and fructo-oligosaccharide, also named oligofructose, from roots of chicory and from tubers of Dahlia and Jerusalem artichoke” (*id.*).

“Inulin consists of chains of fructose units which are mostly or exclusively connected to each other by $\beta(2-1)$ linkages” (*id.* at 2-3).

“Fructo-oligosaccharide or oligofructose, which is in fact a fructan composed of molecules with less than 10 saccharide units, can be obtained by extraction from plant material, by partial hydrolysis, either acidic hydrolysis or enzymatic hydrolysis, of fructans, particularly inulin, as well as by enzymatic synthesis from sucrose” (*id.* at 2).

Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 are pending and on appeal (App. Br. 4).¹ Claim 20 is representative and reads as follows:

20. A method for the treatment of infections in humans or vertebrates comprising:

administering to humans or vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a composition consisting essentially of:

an effective amount of inulin and/or oligofructose to treat said infection; and

one or more pharmaceutically acceptable excipients,
wherein the composition is administered orally or through tube feeding.

THE REJECTION

¹ Appeal Brief filed November 1, 2006.

The Examiner applies the following documents in rejecting the claims:

Paul	US 6,241,983 B1	Jun. 5, 2001
Van Loo	US 6,500,805 B2	Dec. 31, 2002

The following rejection is before us for review:

Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Paul and Van Loo (Ans. 3-4).

OBVIOUSNESS

ISSUE

The Examiner cites Paul as teaching an orally administered composition that contains fructo-oligosaccharides, including inulin, pectins, or pectic polysaccharides (Ans. 3). The Examiner states that Paul discloses “that the disclosed compositions can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as *E. coli*, *Salmonella*, and *Candida*” (*id.*).

The Examiner concedes that Paul does not state the degree of polymerization of the dietary fiber, and cites Van Loo to meet that limitation (*id.*). The Examiner states that Van Loo teaches a fructan- or inulin-containing composition for treating colon cancer that meets the claim limitations regarding degree of polymerization (*id.*).

The Examiner contends that a person of ordinary skill would have been “motivated to combine the two prior art references as they both broadly show that the administration of dietary fiber, such as inulin, is beneficial for the gastrointestinal health of a subject in need thereof” (*id.*). The Examiner

reasons that “[a]s the compositions in both prior art references have similar various effects which are known in the art to [be] beneficial to a subject, one of ordinary skill in the art would have a reasonable chance of success in combining the two references” (*id.*) The Examiner states that beneficial effects of inulin and oligofructose disclosed in the two references “include a reduction of intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism” (*id.* at 3-4).

Appellants contend that that neither Paul nor Van Loo teaches or suggests the limitation, present in each of the appealed independent claims, that requires the patient receiving the inulin and/or oligofructose to have an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* (App. Br. 7-11). Specifically, Appellants contend that one of ordinary skill in the art would understand the infection treated by Paul to be “a local infection in the gastrointestinal tract and . . . not an infection ‘caused by an invasion of the lymph or the blood stream by pathogenic bacteria’” as recited in the appealed claims (*id.* at 9). Appellants further contend that Van Loo is directed to treating colon cancer, and “is absolutely silent with respect to the possible use of inulin and/or oligofructose for the treatment of established infections in humans and vertebrates caused by an invasion of pathogenic bacteria of the lymph or the blood stream” (*id.* at 10-11).

The issue with respect to this rejection, therefore, is whether the Examiner erred in finding that one of ordinary skill viewing Paul and Van

Loo would have considered it obvious to administer inulin and/or oligofructose orally or via feeding tube to a patient infected in the blood stream or lymph with *Clostridia*, *Bacteroides*, *Listeria*, *Candida* or *Salmonella*.

FINDINGS OF FACT

1. Claim 20 recites a method of treating infections in which a composition containing inulin and/or oligofructose is administered orally or via feeding tube to humans or other vertebrates. Claim 20 limits the human or vertebrate patients to those that have an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*.

Claim 27 recites a similar process of orally administering a composition containing inulin and/or oligofructose to humans or other vertebrates to treat an infection of the lymph or blood. Claim 27 limits the treated patients to those “having an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* in the lymph or blood.”

Claim 37 recites a similar process of orally administering inulin and/or oligofructose to treat infection. Claim 37 also limits the patients to those “having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*”

Each of the appealed independent claims therefore limits the treated patients to those that have blood or lymph infected with *Clostridia*, *Bacteroides*, *Listeria*, *Candida* or *Salmonella*.

2. Paul discloses “a composition for use as a dietary supplement that, when ingested, is effective for treating ailments due to gastrointestinal pathogens such as bacteria, viruses, fungi, or protozoa” (Paul, col. 3, ll. 43-46). Paul teaches that the composition contains “an effective amount of dietary fiber. . . . Preferably, the dietary fiber is a member selected from the group consisting of fructo-oligosaccharides, such as inulin . . .” (*id.* at col. 4, ll. 1-5).

3. Paul discloses that the inulin/fructo-oligosaccharide-containing composition also contains “an effective amount of beneficial human intestinal microorganisms” (Paul, col. 3, ll. 66-67), which “are preferably selected from the group consisting of lactobacilli and bifidobacteria” (*id.* at col. 4, ll. 16-17). Paul discloses that “[h]yperproliferation of harmful bacteria in the gut is associated with various forms of diarrhea, susceptibility to systemic infections, constipation, vague and acute abdominal symptoms, fatigue, dyspepsia, and presence of carcinogenic metabolites.

Reestablishment of a normal balance of gastrointestinal flora can be accelerated, and such normal balance maintained, with dietary administration of lactobacilli and/or bifidobacteria” (*id.* at col. 10, ll. 37-45).

Thus, while Paul discloses that the composition can be used to treat gastrointestinal conditions which could lead to systemic infections, Paul does not disclose that systemic infections of the blood or lymph can be treated by orally administering the disclosed inulin/fructo-oligosaccharide-containing composition.

4. Paul discloses that the inulin/fructo-oligosaccharide-containing composition “can be used for maintaining gastrointestinal health as well as

for treating diarrhea, constipation, and other types of gastrointestinal distress due to infection with pathogenic microorganisms such as *E. coli*, Salmonella, Candida, rotavirus, and Cryptosporidium by orally administering an effective amount of the composition” (Paul, col. 16, ll. 22-28). Again, although Paul discloses that the composition can be used to treat gastrointestinal infections caused by microorganisms recited in the appealed claims, Paul does not disclose that infections of the blood or lymph can be treated by orally administering the disclosed inulin/fructo-oligosaccharide-containing composition.

5. Van Loo discloses “the use of compositions comprising certain fructans, preferably certain inulins, for the prevention and/or treatment of colon cancer in non-bovine mammals” (Van Loo, col. 1, ll. 14-17). Van Loo discloses that in a preferred embodiment “the fructan is inulin, preferably with an average degree of polymeri[z]ation of at least 20, even more preferably ranging from 20 to 70” (*id.* at col. 4, ll. 61-63). Van Loo states that benefits in addition to the anti-colon-cancer activity of the compositions include “a reduction of the intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, an increase of the stool weight (bulking) and stool frequency” (*id.* at col. 3, ll. 17-20). Van Loo does not disclose that orally administering the inulin-containing compositions would be useful in treating infections of the blood or lymph.

PRINCIPLES OF LAW

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response,

patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Thus, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning *with some rational underpinning* to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

“The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.” *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991).

ANALYSIS

We agree with Appellants that the Examiner has not shown that Paul and Van Loo would have suggested to one of ordinary skill that inulin and/or oligofructose should be administered orally or via feeding tube to a patient infected in the blood or lymph with *Clostridia*, *Bacteroides*, *Listeria*, *Candida* or *Salmonella*. Paul discloses that an inulin/oligofructose-containing composition is useful for patients having a gastrointestinal infection with pathogens recited in the claims (*see* Findings of Fact 2-4, *supra*). However, we do not see, and the Examiner does not point to, anything in the reference disclosing or suggesting that an infection of the blood or lymph could or should be treated in the same way. Nor do we see anything in the reference disclosing or suggesting that orally administering an inulin/oligofructose-containing composition to a patient would have any effect on blood or lymph infected with *Clostridia*, *Bacteroides*, *Listeria*, *Candida* or *Salmonella*.

We note that Paul discloses that hyperproliferation of pathogens in the gastrointestinal tract can render a patient susceptible to systemic infection, and that an inulin/oligofructose-containing composition that also contains lactobacilli and bifidobacteria can ameliorate that hyperproliferation of pathogens (*see* Finding of Fact 3, *supra*). However, in our view, Paul's disclosure that the composition would be useful in treating a system-weakening gastrointestinal infection does not equate to a disclosure that would have suggested to one of ordinary skill that the composition would also be useful in treating the systemic infection itself.

Similarly, we do not agree with the Examiner that one of ordinary skill would have been prompted to treat a blood or lymph infection by orally administering an inulin/oligofructose-containing composition, based on Van Loo's disclosure that such compositions had a number of gastrointestinal benefits in addition to treating colon cancer (*see* Finding of Fact 5, *supra*). We therefore agree with Appellants that the Examiner has not made out a case of *prima facie* obviousness based on the cited references.

The Examiner argues that “[g]iven that the gastrointestinal tract passes nutrients extracted from food into the blood stream primarily at the large and small intestines, it is unclear how an infection of the gastrointestinal system would not affect the blood stream to some extent” (Ans. 5). The Examiner urges that the “degree to which a pathogen is present in the blood stream or the lymph to fall under what the applicant has termed an ‘invasion’ of such has not been made clear by the applicant” (*id.*).

We are not persuaded by this argument. As discussed above, the claims require the treated patients to be infected in the blood or lymph with

Clostridia, Bacteroides, Listeria, Candida or Salmonella. Even assuming for argument's sake that the claimed infections encompass very small amounts of pathogens in the blood or lymph, the Examiner has not pointed to any evidence of record showing that the gastrointestinal infections treated in Paul, or the colon cancer treated in Van Loo, in any way involve an infection of the blood or lymph.

The Examiner argues that “[c]ertain bacteria such as *Salmonella* are well known to cause severe infections by the ingestion of tainted food by a patient, which is naturally introduced to the body by way of the gastrointestinal system” (Ans. 6). The Examiner reasons that in the case of such severe infections it is “difficult to draw the line of where *Salmonella* poisoning of the gastrointestinal tract is patentably distinct from *Salmonella* poisoning of the blood stream or the lymph” (*id.*).

We are not persuaded by this argument. The Examiner does not point to, and we do not see, any evidence of record showing that severe gastrointestinal infections of the type treated in the Paul reference involve the blood or lymph. The Examiner simply has not shown that the patient population required in the appealed claims coincides in any way with the patients treated in Paul and Van Loo, in a manner suggesting to one of ordinary skill that the claimed patients should be treated with the inulin/oligofructose-containing compositions disclosed in those references. We therefore agree with Appellants that the Examiner has not made out a *prima facie* case of obviousness with respect to the claimed treatment methods.

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Because the Examiner has not shown that the claimed treatment methods would have been prima facie obvious to one of ordinary skill, we reverse the Examiner's rejection of claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 under 35 U.S.C. § 103(a) as obvious in view of Paul and Van Loo.

REVERSED

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